

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: James A. Williams

Serial No.: 08/704,159

Group No.: 1816

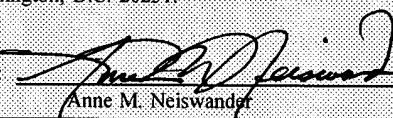
Filed: 08/28/1996

Examiner: Evelyn Rabin

Entitled: **MULTIVALENT VACCINE FOR *CLOSTRIDIUM BOTULINUM* NEUROTOXIN**

**REQUEST FOR WITHDRAWAL OF FINALITY OF  
OFFICE ACTION MAILED OCTOBER 15, 1998**

Assistant Commissioner for Patents  
Washington, D.C. 20231

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)	
I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.	
Dated: <u>4/15/99</u>	By: <u></u> Anne M. Neiswander

Sir:

Applicant respectfully requests withdrawal of the finality of the Office action mailed on October 15, 1998.

The Examiner indicated that the October 15, 1998 Office action, while the first Office action in the instant Continued Prosecution Application, was nonetheless made final because the parent application "could have been finally rejected on the grounds and art of record in the next Office action."<sup>1</sup> However, the "next" (*i.e.*, the second) Office action in the parent application could **not** properly have been made final. The Examiner is instructed by the MPEP that second actions on the merits may **not** be made final if the action includes a rejection, on prior art not of record, of any claim amended to include limitations which should

<sup>1</sup> Office Action, page 8, third full paragraph.

reasonably have been expected to be claimed.<sup>2</sup> The Office action of October 15, 1998 meets this condition, and its finality is thus premature.

The Examiner advanced two rejections under 35 U.S.C. §103(a) on the grounds of alleged obviousness. Each of these rejections rejects claims which have been amended to include reasonably foreseeable limitations, and includes prior art not of record as further discussed below.

**1. LaPenotiere et al. and Nygren et al. are not of record with respect to the combination of the references Thompson et al. in view of Binz et al., Roitt, LeClerc et al., Kleid, and Siegel which were cited against Claims 10-14**

The Examiner finally rejected Claims 10-14 under 35 U.S.C. §103(a) for alleged obviousness over Thompson *et al.* in view of Binz *et al.*, Roitt, LeClerc *et al.*, Kleid, and Siegel.<sup>3</sup> In addition to these references, the Examiner also cited LaPenotiere *et al.* (1993) in support of "knowledge available to [one] of ordinary skill in the art,"<sup>4</sup> as well as Nygren *et al.* (1994) in support of "advantages of recombinant fusion proteins."<sup>5</sup> However, the finality of the action is premature since this rejection is based on newly cited art, and the rejected claims include limitations which the Examiner should reasonably have expected to be claimed. This is further discussed below.

**A. LaPenotiere et al. and Nygren et al. are not of record**

In the first Office action mailed May 28, 1997 in the parent application, the Examiner rejected Claims 10-14 under 35 U.S.C. §103(a) for alleged obviousness over Thompson *et al.* in view of Binz *et al.*, Roitt, LeClerc *et al.*, Kleid, and Siegel. No mention was made of either LaPenotiere *et al.* or Nygren *et al.*, which appear for the **first time** in the Office action mailed October 15, 1998. Thus, each of these two references is newly cited art.

---

<sup>2</sup> MPEP § 707.7(a).

<sup>3</sup> Office Action, page 4, second full paragraph.

<sup>4</sup> Office Action, page 5, second full paragraph.

<sup>5</sup> Office Action, page 6, first full paragraph.

**B. Rejected Claims 10-14 include limitations which the Examiner should reasonably have expected to be claimed**

MPEP § 706.07(b) directs the Examiner that:

"[a] second or any subsequent action on the merits in any application . . . *should not be made final* if it includes a rejection, on prior art not of record, of any claim amended to include limitations which should *reasonably* have been expected to be claimed."<sup>6</sup>

In determining which limitations should reasonably have been expected to be claimed, the Examiner is instructed that such limitations include not only those limitations in the claims, but also all "claimable subject matter" disclosed in the specification and regarded by Applicant as his invention.<sup>7</sup>

The Examiner should reasonably have expected Applicants' amendment of Claim 10 (and thus of dependent originally-filed Claims 11-14).<sup>8</sup> Claim 10 was amended to more clearly describe Applicant's invention by reciting that the fusion protein comprises at least a portion of "one or more," rather than at least a portion of "a," Clostridium botulinum toxin. The claimable limitation of "one or more" Clostridium botulinum toxins was disclosed in the specification under the heading "SUMMARY OF THE INVENTION"<sup>9</sup> which teaches that the:

"The vaccine may be a monovalent vaccine (*i.e.*, containing only a toxin B fusion protein or a toxin E fusion protein), a bivalent vaccine (*i.e.*, containing both a toxin B fusion protein and a toxin E fusion protein) or a trivalent or higher valency vaccinee."<sup>10</sup>

Because the amendment to Claims 10-14 added a limitation that was expressly found in the specification under a heading summarizing the invention, this amendment was reasonably foreseeable.

---

<sup>6</sup> Emphasis added.

<sup>7</sup> MPEP §904.02.

<sup>8</sup> See communication entitled "Amendment and Response to Office Action mailed May 28, 1997" which was mailed to the Office on November 24, 1997.

<sup>9</sup> Specification, page 25.

<sup>10</sup> Specification, page 26, lines 24-27.

Since each of LaPenotiere *et al.* and Nygren *et al.* are newly cited art with respect to amended Claims 10-14 that include limitations which should reasonably have been expected to be claimed, the Examiner's final rejection should be withdrawn.

**2. Nygren et al. is not of record with respect to the combination of the references Thompson et al. in view of Binz et al., Roitt, LeClerc et al., Kleid, Siegel, and Ford et al. which were cited against Claims 13 and 14**

The Examiner finally rejected Claims 13 and 14 under 35 U.S.C. §103(a) for alleged obviousness over Thompson *et al.* in view of Binz *et al.*, Roitt, LeClerc *et al.*, Kleid, and Siegel and further in view of Ford *et al.*<sup>11</sup> In addition to these references, the Examiner also cited Nygren *et al.* (1994) in support of "fusion proteins comprising polyhistidine."<sup>12</sup> This final rejection is improper since, as discussed below, it is based on newly cited art, and the rejected claims include limitations which the Examiner should reasonably have expected to be claimed

**A. Nygren et al. is not of record**

In the first Office action mailed May 28, 1997 in the parent application, the Examiner rejected Claims 13 and 14 under 35 U.S.C. §103(a) for alleged obviousness over Thompson *et al.* in view of Binz *et al.*, Roitt, LeClerc *et al.*, Kleid, and Siegel, and further in view of Ford *et al.* Nygren *et al.* was **not** cited against Claims 13 and 14 in connection with the above-mentioned combination of references. Because Nygren *et al.* is cited for the **first time** in the Office action mailed October 15, 1998, Nygren *et al.* is newly cited art.

**B. Rejected Claims 13 and 14 and 25-28 include limitations which the Examiner should reasonably have expected to be claimed**

As discussed above, the Examiner should reasonably have expected Applicant's amendment of Claims 13 and 14 since this amendment introduced into these claims a limitation which was expressly found in the specification under a heading "SUMMARY OF THE INVENTION."

---

<sup>11</sup> Office Action, page 7, second full paragraph.

<sup>12</sup> Office Action, page 8, first full paragraph.

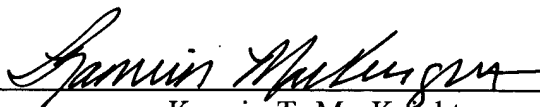
In sum, because each of LaPenotiere *et al.* and Nygren *et al.* are newly cited art with respect to amended Claims 10-14, and Nygren *et al.* is newly cited art with respect of amended Claims 13 and 14, since Claims 10-14 include limitations which should reasonably have been expected to be claimed, the Examiner's final rejection is premature and should be withdrawn.

**Conclusion**

In view of the foregoing, a final Office action in this application is premature and its withdrawal is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at (617) 252-3353

Dated: April 15, 1999



Kamrin T. MacKnight  
Registration No. 38,230

Please direct all communications to:

Peter G. Carroll  
Registration No. 32,837  
MEDLEN & CARROLL, LLP  
220 Montgomery Street, Suite 2200  
San Francisco, California 94104